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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 01-202

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Nancy Joyce Simmons
(Printed Name of Person Sending Correspondence)

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(Signature)

Application Number	Filed
10/075,970	February 14, 2002

First Named Inventor: Michael Helmus

Art Unit	Examiner
3773	Melanie Ruano Tyson

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 34,297
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

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April 17, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[x] *Total of 1 forms are submitted.

Status of the claims

Claims 1, 3, 5-7, 9-21 and 46-50 are pending in this application. Claim 1, the only independent claim presently pending, reads as follows (emphasis added):

> 1. (Previously presented) An implantable or insertable medical device adapted to provide a controlled change in mechanical properties and biomechanical compatibility after being implanted or inserted into a patient comprising a biodegradable inner core material and a *biodegradable covering material completely covering the inner core material*; wherein the biodegradable inner core material is selected from a metallic material and a ceramic material, wherein the covering material substantially controls the rate at which the inner core material becomes flexible upon contact with bodily fluids, wherein after insertion or implantation into a patient, the medical device becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time, wherein said biodegradable covering material does not contain therein a therapeutic agent, and wherein the medical device is substantially biodegradable by the body.

Rejection over Clerc and Bolz

Claims 1, 3, 5-7, 9-21 and 46-48 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Clerc, US 2002/0165601 (Clerc) in view of Bolz et al., US 6,287,332 (Bolz). This rejection is erroneous.

For a proper obviousness rejection, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103(a). The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. " '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' " *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn ,* 441 F.3d 977, 988, (Fed. Cir. 2006). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

According to the Office Action, Clerc discloses an implantable medical device comprising a biodegradable inner core (stent 102) and a biodegradable covering material (106) completely covering the inner core 102 (see Fig. 2A). However, it is clear from Figs. 2A-2B that the covering material 106 only covers the outer (abluminal) surface of the stent 102. The inner (luminal) surface of the stent 102 is exposed to the blood.

As indicated by the Examiner, Clerc describes polycaprolactone as a biodegradable covering material 106. However, because the stent 102 is exposed to the blood, the biodegradable covering material 106 does not completely cover the inner core material as claimed.

As noted by the Examiner, Clerc fails to disclose that the biodegradable inner core material is selected from a metallic material and a ceramic material. The Examiner turns to Bolz, which describes bioresorbable metal stents, to make up for this deficiency in Clerc.

Bolz, however, does not make up for the above noted deficiencies in Clerc. For example, as with Clerc, Bolz fails to teach or suggest a biodegradable covering material that completely covers an inner core material. In addition, Bolz does not teach or suggest a hydrophobic surface erodable polymer for use as a biodegradable covering material (see claims 5 and 48-50). Indeed, Bolz does not teach or suggest polymeric coatings at all.

In response to the preceding argument, the Examiner has argued the following in the Advisory Action mailed March 4, 2009:

> The applicant argues that Clerc's biodegradable covering material is not disposed over the inner (luminal) surface of the stent, thus does not "completely cover" the inner core material. However, nowhere do the claims recite the covering material is disposed on the inner (luminal) surface of the inner core material. The claims simply require a covering material completely covering the inner core material. It is the examiner's position that a covering material completely covering the outer surface of the inner core material satisfies this claim language.

Applicant understands that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." See MPEP 2111, citing the Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005).

However, the Examiner's position that a covering material "completely covering [only] the outer surface of the inner core material" satisfies the language of claim l amounts to an *unreasonable* interpretation.

In this regard, the Examiner's position might have been reasonable had Applicant claimed a biodegradable covering material "completely covering ***a portion of*** the inner core material". However, Applicant has not presented such a claim. Rather applicant is claiming "a biodegradable covering material *completely covering the inner core material*" with no

conditions/qualifications that might otherwise reduce the literal scope of the phrase "completely covering."

The Examiner's statement that "nowhere do the claims recite the covering material is disposed on the inner (luminal) surface of the inner core material" is likewise specious. Of course, Applicant would *not* have drafted such a claim, because a claim wherein the covering material is disposed only on the inner (luminal) surface of the inner core material would clearly be contradictory to the language of claim 1 in which the covering material *completely covers the inner core material.* In this regard, see, 35 USC 112, 4th paragraph, ("a claim in dependent form shall contain a reference to a claim previously set forth and then specify a *further limitation* of the subject matter claimed"). The claim proposed by the Examiner, in which the covering material is present *only on the inner surface* of a tubular inner core material would not further limit claim 1 in which the covering material *completely covers* the inner core material.

For at least the above reasons, withdrawal of the outstanding rejection under 35 U.S.C. 103(a) are is respectfully requested.